

# **Overview of Medical Use of Marijuana Program Proposed Testing Protocols**

**November 19, 2015**

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- Approach Comparison
- Benefits of Proposed Approach
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# Rationale for Protocol Review

1. Takes advantage of new technical information gleaned from evolving database of scientific literature.
2. Considers written comments from stakeholders (i.e., RMDs, laboratories, patient advocates, government officials).
3. Incorporates feedback from listening sessions with labs and RMDs.

# Overview of Proposed Changes

1. Adopt new Heavy Metal Limits consistent with United States Pharmacopeia (USP) upper concentration limits
2. Increase the Residual Solvent Limits to bring them in alignment with USP concentration limits
3. Require product labeling to specify the amount of product that has been evaluated as safe for consumption (i.e., 0.35 oz. or 10 g/day)
4. Require product labeling to specify the route of exposure that the product has been evaluated for (i.e., ingestion only; all other uses)

# Approach Comparison

## Original Approach

- Based upon AHP standards for herbal supplements
- Based upon “risk assessment” worst case scenario
- Assumption of 28.4 g/day of plant material consumed
- Route of exposure not specified and thus inclusive of all routes
- No labeling requirement. Approach very conservative/protective.

## Proposed Approach

- Based upon USP standards for drugs and nutritional supplements
- Reasonable Maximum Exposure (RME) assumptions based on usage
- Sets exposure to 10 g/day based on review of a dozen credible studies
- 2 sets of standards: ingestion, all routes (ingestion, inhalation, and dermal)
- Labeling specifies both safe amount of exposure product is tested safe for and route of consumption

# Benefits of Proposed Approach

- By moving to USP standard, DPH references “living levels” that are consistently revised and based upon evolving science, analytical capabilities, and other new information
- More versatile as route of exposure yields two different maximum levels thus tailoring levels to product type
- Similar to recommended daily dosage labeling on medications thus emphasizing the importance of patient ownership
- Consistent with approach used by FDA compliant evaluation of drugs, medical devices and supplements
- Detailed product labeling specifies the amount of product that has been evaluated as safe as well as route of exposure evaluated for

- November 19, 2015: Proposed Protocols released
  - Posted on DPH website
  - Public Comment period begins
  - Current Protocols and Waiver process remain in effect
- December 17, 2015: Public Comment Period ends
  - DPH assesses feedback, reserves right to follow-up with requests for additional information
- January 11, 2015: Anticipated date for Final Protocol release
  - Posted on DPH website
- March 31, 2015: Anticipated date Protocols become effective
  - Testing results held to new levels based on USP standards

# Public Comment Period

- DPH welcomes and encourages feedback
  - Email comments to [RMDCompliance@state.ma.us](mailto:RMDCompliance@state.ma.us)
  - Mail comments to Program (address on last slide)
- DPH available for technical questions
  - Email comments to [RMDCompliance@state.ma.us](mailto:RMDCompliance@state.ma.us)
  - Priority will be placed on timely response

Public comments and technical questions should be directed to:

Via Email: [RMDCompliance@state.ma.us](mailto:RMDCompliance@state.ma.us).

Via Mail: Medical Use of Marijuana Program  
Attn: RMD Compliance  
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